

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

**IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION**

This Document Relates to:

Wray v. Ameridose, LLC, et al.

MDL No. 2419

Dkt. No 1:13-cv-12737

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO THE TENNESSEE
CLINIC DEFENDANTS' MOTION FOR QUALIFIED PROTECTIVE ORDER**

Plaintiffs submit this Memorandum of Law in opposition to the Tennessee Clinic Defendant's Motion for a Qualified Protective Order. [Dkt. No. 50.]¹

Regardless how Defendants try to dress it up, this is a procedural discovery dispute about the issuance of a protective order allowing informal discovery of third parties – in this instance, Plaintiffs' treating physicians with whom Plaintiffs have a federally protected confidential relationship. Tenn. Code Ann. § 29-26-121(f) (hereinafter “121(f)”) is, on its face, a procedural rule governing discovery matters, and as such is in direct conflict with Fed. R. Civ. P. 26(c). And it is undisputed that federal courts must apply federal procedural law where, as here, the comparative state law directly conflicts with the federal rule.

Even if 121(f) did not directly conflict with Fed. R. Civ. P. 26(c) (which it does), it would be inapplicable in this case because it is preempted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the rules promulgated by the United States Department of Health and Human Services pursuant to HIPAA.

¹ Defendants filed this motion only on the individual case docket for *Wray v. Ameridose, LLC, et al.*, Case No. 1:13-cv-12737. This is an issue, however, that impacts most or all Tennessee cases and will recur.

Here, Defendants' attempted use of 121(f) would effectively empower a state legislature to direct how a federal district court manages discovery, running afoul of federalism principles. In crafting the language for 121(f), Tennessee legislature evidently attempted to circumvent HIPAA's protection of patient health information – but they failed. In short, 121(f) is preempted by HIPAA. And moreover, the Tennessee statute notwithstanding, HIPPA itself does not allow *ex parte* interviews of the type Defendants' are requesting.

It is clear that Defendants are seeking these intrusive and secret meetings with Plaintiffs' physicians to gain an unfair advantage in the discovery process. There is no information they could learn from those interviews that they could not get through the formal discovery procedures provided under the Federal Rules of Civil Procedure. It is further evident that Defendants' purpose for seeking the secret meetings is to create an opportunity to influence the physicians' testimony: Plaintiffs offered to allow the interviews, so long as Plaintiffs' counsel were present to protect the Wrays' interests during the interview.² This procedure would have cured many of the privacy and supervision risks discussed below. But Defendants refused out-of-hand, making clear that their intended purpose extends far beyond gathering information.

I. ARGUMENT

A. Protective Orders Are Procedural Discovery Devices to Which Federal Law Applies.

1. Section 121(f) is a Procedural Discovery Rule

Defendants incorrectly aver that Tenn. Code Ann. § 29-26-121(f) in its entirety is substantive and applicable to this matter. Defendants cite no case law holding that § 121(f) is substantive; to the contrary, it is a procedural discovery rule concerning protective orders for

² See Exhibit A, attached hereto.

informal discovery interviews, and as such should only be applied to the extent that it does not conflict with federal procedural discovery rules.

Tenn. Code Ann. § 29-26-121(f) provides a procedure for seeking a qualified protective order allowing *ex parte* interviews of a plaintiffs' treating physicians.³ Protective orders – the process for requesting them and the criteria for considering such requests – are undisputedly matters of discovery procedure.⁴ Moreover, *ex parte* interviews themselves (separate and apart from protective orders) are frequently characterized as a method of informal discovery.⁵ It follows that a rule concerning *ex parte* interviews “regulates only how defense counsel may obtain information from a plaintiff’s treating physician, i.e., it affects defense counsel’s methods, not the substance of what is discoverable.” *Alsip*, 197 S.W.3d at 727 (internal quotation omitted).⁶

Further, in Tennessee, “[a] statute is procedural if it defines the mode or proceeding by which a legal right is enforced, as distinguished from the law which gives or defines the

³ See Tenn. Code Ann. § 29-26-121(f)(1) (“...the named defendant or defendants **may petition the court for a qualified protective order allowing** the defendant or defendants and their attorneys the right to obtain protected health information during interviews, outside the presence of claimant or claimant’s counsel, with the relevant patient’s treating ‘healthcare providers’ ...”).

⁴ This is why protective orders are governed by rules of discovery **procedure** on both the federal and state levels. See Fed. R. Civ. P. 26(c); Tenn. R. Civ. P. 26.03.

⁵ See, e.g., *Weaver v. Mann*, 90 F.R.D. 443, 445 (D.N.D. 1981) (characterizing *ex parte* interviews as a method of informal discovery to be governed by federal rather than state law); *Garner v. Ford Motor Co.*, 61 F.R.D. 22, 24 (D. Alaska 1973) (same).

⁶ For this reason, too, FRE 501 does not apply here, contrary to Defendants’ contention. See Defs’ Mem. 9-10. This is a rule about discovery; FRE 501 concerns privilege. Contrary to Defendants’ argument, 121(f) is not a statutory exemption to the patient-physician privilege rule, because there exists no general physician-patient privilege in Tennessee at common law or by statute. See, e.g., *Alsip v. Johnson City Med. Ctr.*, 197 S.W.3d 722, 725 (Tenn. 2006); see also Existence of a physician-patient privilege, Trial Handbook for Tenn. Law § 18:11. Tennessee has only a common law implied covenant of confidentiality between patient and physician, *Givens v. Mullikin ex rel. Estate of McElwaney*, 75 S.W.3d 383 (Tenn. 2002) (which may be the reason 121(f) does not use the word “privilege” anywhere in its text). Privilege and confidentiality are two separate concepts. FRE 501 applies only to privilege and so does not apply here.

right....”⁷ Here, Tenn. Code Ann. § 29-26-121(f) does not confer the right to conduct *ex parte* interviews, as Defendants would have it. Rather, it sets forth the *procedure* by which a defendant can ask the court to enter a protective order – and it is that court order (if defendant’s motion is granted) that actually confers the right to conduct the interviews. The statute itself, standing alone, confers nothing but the opportunity to ask the court for a protective order and the procedure for doing so.⁸ The reason for this is clear from the legislative history of the statute. In fact, 121(f) was carefully drafted so as *not* to confer the right to *ex parte* interviews – because if it did, it would have squarely conflict with HIPAA. So, in an attempt to avoid direct conflict with HIPAA, the Tennessee legislature purposefully attempted to draft the statute to *avoid* conferring a right, and to instead provide a procedural roadmap to technically mimic HIPAA’s procedure while in effect forcing the court’s hand to grant the protective order allowing *ex parte* interviews. This legislative history underscores that 121(f) is – and indeed was intentionally drafted to be – a procedural discovery rule.

2. This Court Recognizes It Must Apply Federal Law to Procedural Matters.

It is well-settled that federal courts exercising jurisdiction over state law claims—whether diversity jurisdiction, pendent jurisdiction, or related-to bankruptcy jurisdiction—generally apply

⁷ *Kuykendall v. Wheeler*, 890 S.W.2d 785, 787 (Tenn. 1994) (internal quotations omitted).

⁸ Defendants cite *Dean-Hayslett v. Methodist Healthcare*, 2015 WL 277114, at *12 (Tenn. Ct. App. Jan. 20, 2015), *appeal denied* (Aug. 17, 2015), in support of their motion. That case was decided by a Tennessee state court applying Tennessee rules and law. The Tennessee Court of Appeals noted, however, that 121(f) is a procedural statute that permits a Tennessee state court to act under its inherent authority: “[121(f)] authorizes a pretrial investigatory **procedure** that nevertheless requires a court order, and Tennessee common law has long recognized the broad inherent authority of trial courts to control proceedings in their courts.” Moreover, the Court did not address with any meaningful analysis the contention that HIPAA preempts 121(f). In short, *Dean-Hayslett* has no application here.

state law to substantive issues, but federal law to matters of procedure.⁹ Where – as here – the state law in question directly conflicts with a federal procedural rule, the court must apply the federal rule unless it is unconstitutional.¹⁰

Here, 121(f) is a state procedural discovery rule that directly conflicts with Federal Rule of Civil Procedure 26(c) because its mandate that a court enter a qualified protective order if certain conditions are met abrogates the federal court’s discretion to grant protective orders and, more broadly, to manage the procedure and content of discovery, as well as guard against discovery abuses.¹¹

More pointedly, the Court under HIPAA has broader discretion to deny the petition for qualified protective order than under 121(f). Federal Rule of Civil Procedure 26(c) governs the Court’s discretion to issue a protective order, and provides several avenues by which the Court can deny or condition protective orders. Ultimately, the rule places the burden on the requestor/Defendants to show good cause why the health information should be released *ex parte*.¹² Contrast the federal rule requiring the petitioning party to show good cause for entry of a protective order with the Tennessee statute, which places the burden of avoiding a protective

⁹ See, e.g., *In re New England Compounding Pharmacy, Inc. Products Liab. Litig.*, No. MDL 13-02419-RWZ, 2014 WL 6676061, at *3 (D. Mass. Nov. 25, 2014) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938) and *In re Johnson*, 453 B.R. 433, 436 (Bankr.M.D.Fla.2011) (jurisdiction under 28 U.S.C. § 1334(a) and (b)) among others).

¹⁰ *Id.* (citing *Hanna v. Plumer*, 380 U.S. 460, 463–471, 85 S.Ct. 1136, 14 L.Ed.2d 8 (1965)).

¹¹ *Id.* (finding state law discovery rule did not apply in federal court because it was a procedural statute that conflicted with the Federal Rules of Civil Procedure and thereby abrogated district court’s discretion to manage discovery and administer sanctions).

¹² In relevant part, Rule 26 states: “A party or any person from whom discovery is sought may move for a protective order in the court where the action is pending--or as an alternative on matters relating to a deposition, in the court for the district where the deposition will be taken. The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action. The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” Fed. R. Civ. P. 26(c).

order on the Plaintiff/patient. The federal rule is by far more protective of a patient's confidential health information.¹³

Moreover, all the information Defendants could hope to get from *ex parte* interviews is available through formal discovery under the Federal Rules of Civil Procedure.¹⁴ Numerous "courts [have] concluded that formal discovery procedures enable defendants to reach all relevant information while simultaneously protecting the patient's privacy by ensuring supervision over the discovery process...." *Alsip*, 197 S.W.3d at 727 (internal quotation omitted); *see also State ex rel. Kitzmiller v. Henning*, 437 S.E.2d 452, 456 (W. Va. 1993) ("No reason other than expense has been suggested or occurs to us to justify the unwarranted (unauthorized) disclosures of confidential information in private nonadversary interviews and we believe that

¹³ Alternatively under HIPAA, the requestor may provide "satisfactory assurance" to the health care provider that the requestor gave adequate notice to the subject of the request. 45 CFR 164.512. However, this provision is still more protective of a Plaintiff because it requires requestors of protected healthcare information to resolve any objections to the request raised by the patient. "Satisfactory assurance" is defined as a written statement demonstrating that (1) the requestor notified the subject in good faith, (2) the notice had sufficient information about the litigation, and (3) the subject had sufficient time to raise and resolve any objections. In contrast, under the Tennessee law, the only way to avoid a grant of the Defendant's petition for a protective order is to file an objection showing "good cause that a treating healthcare provider does not possess relevant information as defined by the Tennessee Rules of Civil Procedure." Tenn. Code Ann. § 29-26-121(f)(1)(B). That standard is simply not protective of a Plaintiff's right to confidentiality.

¹⁴ *See, e.g., Alsip*, 197 S.W.3d at 726-28 (finding that prohibiting defendants from communicating *ex parte* with non-party physicians would not impede defendants from learning all the plaintiff's relevant medical information, because defendants could obtain any and all relevant information via formal discovery procedures); *see also Weaver v. Mann*, 90 F.R.D. 443, 445 (D.N.D. 1981) (same); *Garner v. Ford Motor Co.*, 61 F.R.D. 22, 23-24 (D. Alaska 1973); *King*, 798 F. Supp. at 1373; *Roberson v. Liu*, 555 N.E.2d 999, 1002 (Ill. App. Ct. 1990); *Petrillo v. Syntex Labs., Inc.*, 499 N.E.2d 952, 956 (Ill. App. Ct. 1986) (stating that formal discovery reveals the same information that informal methods reveals); *Karsten v. McCray*, 509 N.E.2d 1376, 1384 (Ill. App. Ct. 1987) (stating that a party can obtain the same information through formal discovery as can be obtained through informal methods which supports the use of discovery to protect a privileged communication); *Anker v. Brodnitz*, 413 N.Y.S.2d 582, 583 (N.Y. Gen. Term 1979) (noting that the defendant did not demonstrate that formal discovery procedures were inadequate to uncover the specific information sought by *ex parte* communication).

the potential abuses of *ex parte* interviews is so enormous that expense alone is no reason to accede to the hospital’s request.”).

Section 121(f) is a state procedural discovery rule, which directly conflicts with Fed. R. Civ. P. 26, and thus federal procedural law must be applied here. For this reason alone, Defendants’ motion should be denied.

3. Section 121(f) is Preempted by HIPAA

Another reason Defendants’ motion should be denied is because HIPAA preempts 121(f). Defendants’ argument here is that HIPAA does not expressly prohibit *ex parte* interviews so therefore 121(f) is not contrary to HIPAA. Defs’ Mem. 7. But Defendants – and the authorities they rely on – fail to engage in a full and proper preemption analysis.¹⁵ More specifically, Defendants and their authorities fail to acknowledge and properly apply the “obstacle test” in HIPAA’s express preemption provision.¹⁶ And it is under the “obstacle test” that 121(f) is contrary to HIPAA.

Congress enacted HIPAA in 1996 to protect patients’ health information and to govern the dissemination of protected health information in all its forms - written, electronic, or oral (including testimony).¹⁷ To do so, HIPAA invokes the authority provided by the Supremacy Clause and expressly preempts all “contrary” state laws.¹⁸ HIPAA’s preemption provision

¹⁵ Some Federal courts have held that the absence of a rule permitting the interviews prohibits them. *See, e.g., Neubeck v. Lundquist*, 186 F.R.D. 249, 251 (D. Me. 1999) (holding that defendants must remain within the strictures of the “formal mechanisms of discovery provided by the Federal Rules of Civil Procedure absent the express consent of a plaintiff”).

¹⁶ *See* Defs’ Mem. 7-8.

¹⁷ *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.)

¹⁸ 45 C.F.R. § 160.203 (2012) (“A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law.”). Although the preemption provision was enacted by the Secretary through regulations, Congress implicitly authorized preemption in its notes to HIPAA: “A regulation shall not supercede [sic] a contrary provision of State law, if the provision of State law imposes

ensures that the federal protections “set forth the baseline for the release of health information.”¹⁹

Importantly, however, HIPAA sets only a floor and not a ceiling for privacy protections;

therefore, HIPAA only preempts state laws that provide less stringent protections for an

individual’s health information than those required by federal law.²⁰

To determine whether a state law is preempted by HIPAA, one must first determine whether the state law is actually “contrary” to HIPAA’s provisions. HIPAA expressly authorizes the use of “conflict preemption,” which consists of two equally weighted tests for determining when a state law is “contrary” to HIPAA’s requirements.²¹ First, under the “impossibility test,” a state law is preempted if it is impossible for the health care provider to comply with both HIPAA and the applicable state law. Second, under the “obstacle test,” a state law is preempted when it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of” HIPAA.²² This language, which defines the scope and applicability of the “obstacle test,” is

requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.” Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264(c)(2), 110 Stat. 1936, 2033-34 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

¹⁹ *Law v. Zuckerman*, 307 F. Supp. 2d 705, 708 (D. Md. 2004).

²⁰ 45 C.F.R. § 160.203(b); *Alsip v. Johnson City Med. Ctr.*, 197 S.W.3d 722, 727 (Tenn. 2006) (“Federal law clearly provides that the provisions of HIPAA and its related rules, where more stringent or, stated another way, more confidentiality-friendly, preempt the less stringent edicts of state law; while states can establish greater protections than those provided for under HIPAA, they cannot promulgate rules that provide for less stringent protections.”)

²¹ See 45 C.F.R. § 160.202; see also *English v. Gen. Electric Co.*, 496 U.S. 72, 79 (1990) (explaining that implied conflict preemption exists where “it is impossible for a private party to comply with both state and federal requirements or where state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress’ (citations omitted) (quoting *Hines v. Davidowitz*, 312 U.S. 52 (1941))).

²² See 45 C.F.R. § 160.202(2); see also *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 491-92 (1987) (“A state law is also pre-empted if it interferes with the methods by which the federal statute was designed to reach [its] goal.”).

intentionally closely tracked by the second prong of HIPAA's express preemption provision and was relied upon in devising the parameters of HIPAA's preemption of state law.²³

Generally, HIPAA prohibits a physician from disclosing protected health information absent the patient's consent.²⁴ The limited circumstances under which a physician may disclose protected health information without the patient's consent are laid out in HIPAA's Privacy Rule.²⁵ Here, the question is whether 121(f) is contrary to HIPAA's Privacy Rule under either the "impossibility test" or the "obstacle test".

It is arguable that the TN legislature was successful in carefully wording 121(f) such that it passes the "impossibility test." In other words, based purely on the text of the Privacy Rule, conceivably a treating physician could technically comply with both the procedural requirements of the Privacy Rule and 121(f).²⁶

But the "impossibility test" is not the end of the inquiry. Even where it is not impossible to comply with both federal and state law, the state law may still be preempted if it fails the

²³ Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,997 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-64) ("This [obstacle] test is particularly relevant with respect to HIPAA regulations, where Congress clearly intended uniform standards to apply nationwide.").

²⁴ 45 C.F.R. § 164.508(a)(1) ("Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section.").

²⁵ See *id.* § 164.512.

²⁶ In order to do so, a physician must ensure (1) that defense counsel has secured a qualified protective order that expressly authorizes the physician to divulge certain health information; and (2) that the order restricts the disclosures to the context of the pending litigation and mandates that defense counsel return or destroy all information obtained from the treating physician at the conclusion of the lawsuit. Compare Tenn. Code Ann. § 29-26-121(f), with 45 C.F.R. § 164.512(e)(1)(v). The fact that defense counsel has secured the qualified protective order ensures that the plaintiff had notice and an opportunity to object. Compare Tenn. Code Ann. § 29-26-121(f)(1)(B), with 45 C.F.R. § 164.512(e)(1)(ii).

“obstacle test.”²⁷ In other words, even where a state law is seemingly in compliance with the Privacy Rule on its face, it may still be preempted if it interferes with the objectives and purposes of HIPAA. Accordingly, the “obstacle test” continues to uphold Congress’s stated purpose of protecting patients’ privacy rights in situations where the “impossibility test” fails to do so due to “carefully crafted” state laws that do not expressly conflict with the relevant federal provisions.

While the impossibility test is the proper vehicle for analyzing simple textual compliance, the obstacle test must be used, too, to analyze compliance with HIPAA’s underlying extratextual objectives. Although the Privacy Rule seeks to strike a balance between patient privacy and necessary disclosures, it is undisputed that HIPAA’s primary goal is to protect the privacy of a patient’s health information – so the question here is whether section 121(f) stands as an obstacle to this goal. This requires analyzing whether section 121(f) prevents the Privacy Rule from providing adequate protection for health information and, if so, whether the reduced confidentiality that occurs as a result of the additional disclosure is justified. And HIPAA’s express invocation of obstacle preemption requires a reviewing court to give heavy weight to HIPAA’s compelling interest in protecting private health information, a compelling interest that outweighs the unsubstantiated state or personal interests in litigation discovery.²⁸

Here, 121(f) fails the obstacle test because it is less stringent than HIPAA and, therefore, stands as an obstacle to HIPAA’s primary goal of providing a baseline level of protection for the privacy of a patient’s health information.

²⁷ See 45 C.F.R. § 160.202(2) (2012). In order for the obstacle test to have any effect at all, it must be true that the Privacy Rule can preempt certain state laws despite the fact that a law passes the impossibility test; otherwise, there would be no reason to have a second definition of “contrary.”

²⁸ See e.g. *EEOC v. Boston Market Corp.*, No. CV 03-4227, 2004 WL 3327264, at *5 (E.D.N.Y. Dec. 16, 2004) (holding that issuing an order permitting *ex parte* interviews with the plaintiff’s treating physicians would be a serious violation of the “strong federal policy in favor of protecting the privacy of patient medical records.”)

First, 121(f) appears to remove all privacy protections—at least in the context of the ongoing litigation—for the Plaintiffs’ health information by deeming all disclosures made pursuant to a qualified protective order “permissible under Tennessee law.”²⁹ Absent the effect of 121(f)(2), a treating physician’s disclosure of non-discoverable, irrelevant health information would be improper and would subject the treating physician to a suit for breach of the implied covenant of confidentiality.³⁰ Section 121(f), however, immunizes the physician from any disclosure that would typically be improper, so long as the disclosure is made in an interview authorized by a qualified protective order. In other words, once a protective order has been secured, 121(f)(2) permits the physician to disclose *any* of the plaintiff’s health information. This clearly impermissibly lowers the protective floor that Congress sought to provide in enacting HIPAA.³¹ This point is bolstered by HIPAA’s requirement that treating physicians who choose to disclose health information to divulge only the “minimum necessary” to comply with the request.³² Discussion of irrelevant information that is normally subject to the implied covenant of confidentiality under Tennessee law does not meet this minimally necessary requirement, but these disclosures would nonetheless be permitted by section 121(f)(2) in an *ex parte* interview, putting 121(f) at odds with HIPAA.

Second, 121(f)’s requirement that patients bear the burden of dissuading the court from granting a protective order regarding *ex parte* interview is absolutely at odds with HIPAA’s

²⁹ See Tenn. Code Ann. § 29-26-121(f)(2) (2012).

³⁰ See *Alsip v. Johnson City Med. Ctr.*, 197 S.W.3d 722, 729 (Tenn. 2006); *Givens v. Mullikin ex rel. Estate of McElwaney*, 75 S.W.3d 383, 407-09 (Tenn. 2002).

³¹ 45 C.F.R. § 164.512(e)(1)(i) (2012) (requiring that the treating physician disclose “only the protected health information expressly authorized by [the protective] order”). The risk to the plaintiff’s privacy is further compounded by the apparent ease with which defense counsel may secure a qualified protective order. See Tenn. Code Ann. § 29-26-121(f)(1)(B) (placing the burden on plaintiff to demonstrate that a treating physician possesses no discoverable information).

³² 45 C.F.R. § 164.502(b)(1).

method, which places the burden on the requestor to show that an *ex parte* interview is necessary. If Tennessee legislators wanted to mirror the policy ends contemplated by HIPAA, they would have done so. Instead, their intent was to loosen protections for health information and make it easier for defendants to conduct *ex parte* interviews. This is the very reason why HIPAA methods should be applied to the matter at hand.

Third, 121(f)(2) fails to provide any oversight of defense counsel and the physician during the *ex parte* interview process, and prohibits a patient from seeking recourse against the treating physician for any irrelevant disclosures—assuming she even discovers an irrelevant disclosure.³³ As recognized by the Tennessee Supreme Court, neither a physician nor defense counsel is capable of determining whether the requested information is relevant to the pending litigation.³⁴ That no one is present to competently arbitrate the relevancy of the divulged information is especially important in the context of private health information because the harm lies in the disclosure itself.³⁵ Without the supervision of either the court or plaintiff's counsel, there is a serious risk that defense counsel “may abuse his opportunity to interrogate the physician by privately inquiring into facts or opinions concerning the patient’s mental and physical health or history which may neither be relevant to the patient’s lawsuit nor lead to

³³ See *Crenshaw v. MONY Life Ins. Co.*, 318 F. Supp. 2d 1015, 1029 (S.D. Cal. 2004) (explaining that “HIPAA does not authorize *ex parte* contacts with healthcare providers,” particularly where there is no safeguard to protect the patient’s privacy); *State ex rel. Proctor v. Messina*, 320 S.W. 2d 146, 156 (Mo. 2010) (*en banc*); *Horner v. Rowan Cos. Inc.*, 153 F.R.D. 597, 601 (S.D. Tex. 1994) (“[T]he potential for breaches in confidentiality can have a chilling effect upon the critically important underlying relationship.”); *Roberson*, 555 N.E.2d at 1002; *Petrillo*, 499 N.E.2d at 959; See *Anker*, 413 N.Y.S.2d at 585 (stating that physicians may be wrongfully pressured into revealing privileged information); *Manion v. N.P.W. Med. Ctr. of Ne. Pa., Inc.*, 676 F. Supp. at 595 (M.D. Pa. 1987); *Horner v. Rowan Cos.*, 153 F.R.D. 597, 600 (S.D. Tex. 1994).

³⁴ See, e.g., *Alsip*, 197 S.W.3d at 728-29.

³⁵ See *Joshua D.W. Collins, Toothless HIPAA: Searching for a Private Right of Action to Remedy Privacy Rule Violations*, 60 VAND. L. REV. 199, 201 (2007) (discussing “the potentially devastating results of improper disclosures” in the context of medical privacy).

discovery of admissible evidence.”³⁶ The *ex parte* interview deprives the plaintiff of the ability to object to “irrelevant inquiries.”³⁷ Moreover, neither defense counsel nor the treating physician is in a position to decide what information is relevant.³⁸ The treating physician is not an attorney and is therefore not qualified to act as the arbiter of relevant information, and defense counsel cannot know in advance the substance of the information he seeks to elicit. Further, courts are concerned that the physician may disclose information to defense counsel that he may not have even communicated to the plaintiff.³⁹

Other state courts have strictly construed the Privacy Rule to find that it does not encompass or permit informal discovery techniques, such as *ex parte* interviews, that are not undertaken with the plaintiff’s consent.⁴⁰ Requiring formal discovery procedures protects the

³⁶ *Alsip*, 197 S.W.3d at 728 (quoting *Wenninger v. Muesing*, 240 N.W.2d 333, 336-337 (Minn. 1976)); *see also Browne v. Horbar*, 792 N.Y.S.2d 314, 319 (Sup. Ct. 2004) (“Private interviews outside the patient or patient representative’s presence present very troubling confidentiality problems.”); *State ex rel. Woytus v. Ryan*, 776 S.W.2d 389, 395 (Mo. 1989) (noting, even prior to the enactment of HIPAA, that “*ex parte* discussion creates an opportunity for the consideration of extrinsic matters that may subtly compromise a physician’s duty of loyalty to the patient” (citing *Manion*, 676 F. Supp. 585, 594-95)).

³⁷ *See Alsip*, 197 S.W.3d at 728 (citing *Karsten v. McCray*, 157 Ill. App. 3d 1, 14 (App. Ct. 1987)).

³⁸ *Roosevelt Hotel Ltd. P’ship v. Sweeney*, 394 N.W.2d 353, 357 (Iowa 1986) (prohibiting *ex parte* interviews prior to enactment of HIPAA: “We are concerned with the difficulty of determining whether a particular piece of information is relevant to the claim being litigated. Placing the burden of determining relevancy on an attorney, who does not know the nature of the confidential disclosure about to be elicited, is risky. Asking the physician, untrained in the law, to assume this burden is a greater gamble and is unfair to the physician. We believe this determination is better made in a setting in which counsel for each party is present and the court is available to settle disputes.”)

³⁹ *Browne*, 792 N.Y.S.2d at 319.

⁴⁰ In *State ex rel. Proctor v. Messina*, 320 S.W.3d 145, 152-55 (Mo. 2010), the Missouri Supreme Court held that the Privacy Rule restricts permissible disclosures solely to those made “in a judicial or administrative proceeding,” which would require that the disclosure be made pursuant to a formal discovery request or another court procedure utilizing the supervisory authority of the judiciary system. According to this court, an *ex parte* interview does not occur in a judicial or administrative proceeding because “the trial court has no general oversight of the meeting or any control over it.”

court's supervisory authority over the disclosure to ensure that all information discovered is within the permissible limits of the patient's privacy rights, as well as the Rules of Civil Procedure.

The privacy protections that Congress contemplated when enacting HIPAA certainly do not permit a treating physician to divulge any and all of the plaintiff's health information without any supervision or consideration of the context in which the information is sought.⁴¹ To find otherwise would leave the plaintiff with no protection of his health information at all, as if HIPAA had never been enacted.

Congress enacted HIPAA to guard against these risks, and the application of the impossibility test, without the obstacle test, fails to fully analyze whether congressional goals are being carried out. Section 121(f) does not pass the obstacle test and therefore is preempted by HIPAA.

4. HIPAA does not permit *ex parte* interviews

Contrary to Defendants' contention, HIPAA does not permit *ex parte* interviews. There are many examples of courts finding that HIPAA implicitly prohibits *ex parte* defense counsel interviews with treating physicians. *See, e.g., Piehl v. Saheta*, No. CCB-13-254, 2013 WL 2470128, at *2 (D. Md. June 5, 2013) (quoting 45 C.F.R. § 165.512(e)(1)(i) (2012)) (finding that HIPAA prohibits *ex parte* defense counsel interviews with treating physicians, in part, because HIPAA allows only “‘expressly authorized,’ limited, and specifically identified protected health

⁴¹ Even in the context of litigation, these potential disclosures may have the undesirable impact of chilling the physician-patient relationship and preventing effective health care. Collins, *supra* at 202; Ronald A. Parsons, Jr. & Shannon R. Falon, *Ex parte* Contacts Revisited, 58 S.D. L. REV. 273, 286 (2013) (“[A] llowing such communications undermines the patient's confidence that sensitive medical information will be protected, and therefore imperils the medical relationship.”).

information” which would likely be violated in an *ex parte* interview; and because Congress created a heightened privacy interest in medical information).

Further, the Federal Rules of Civil Procedure do not expressly permit *ex parte* defense interviews. *See King v. Ahrens*, 798 F. Supp. 1371, 1373 (W.D. Ark. 1992), aff’d 16 F.3d 265 (8th Cir. 1994) (noting that cases prohibiting *ex parte* communication point to the rules that authorize deposition of treating physicians and thus only permit formal discovery); *Weaver v. Mann*, 90 F.R.D. 443, 445 (D.N.D. 1981) (stating that the federal rules of civil procedure allow for several methods “by which discovery of examining physicians may be obtained”); *Roosevelt Hotel Ltd. P’ship v. Sweeney*, 394 N.W.2d 353, 356 (Iowa 1986) (“Our rule speaks only to depositions, interrogatories, production of documents, inspection, physical and mental examination, and requests for admissions The addition of a new discovery method, the court enforced waiver of privilege leading to *ex parte* informal interviews with physicians, should be accomplished by a change in the Rules of Civil Procedure, rather than by judicial fiat.”); *State ex rel. Woytus v. Ryan*, 776 S.W.2d 389, 392 (Mo. 1989) (noting that Missouri rules do not expressly forbid *ex parte* communication, but also do not expressly authorize communication); *Jaap v. Dist. Ct. of the Eighth Jud. Dist.*, 623 P.2d 1389, 1392 (Mont. 1981) (holding that methods of discovery not permitted by the Montana Rules of Civil Procedure cannot be enforced by the court); *Stoller v. Moo Young Jun*, 499 N.Y.S.2d 790, 791 (N.Y. App. Div. 1986) (holding that defendants are not entitled to conduct unauthorized private interviews with nonparty treating physicians); *Anker v. Brodnitz*, 413 N.Y.S.2d 582, 584 (N.Y. Sup. Ct. 1979) (“[T]he better rule denies defendant the right to question plaintiff’s doctors outside formal discovery procedures.”); *State ex rel. Klieger v. Alby*, 373 N.W.2d 57, 60-61 (Wis. App. 1985) (stating that the definition of discovery under Wisconsin law does not include *ex parte* conferences).

5. Defendants Failed to Show Good Cause for *Ex parte* Interviews.

HIPAA, read together with its regulations and Fed. Rule of Civ. P. 26, mandates that Defendants show *good cause* in order to obtain the requested protective order. Plaintiffs do not dispute that HIPAA does not expressly prohibit *ex parte* interviews. However, HIPAA does expressly require that the petitioning party obtain a protective order which may only be issued subsequent to a showing of good cause or substantial assurances (discussed above).

Defendants have not established good cause. Nowhere in Defendants' papers do they set forth a reason (much less a good reason) why this Court should allow them to invade Plaintiffs' confidential relationship with their physicians, through *ex parte* meetings unfettered by the protections of the Federal Rules. Plaintiffs have scheduled depositions with some of Mrs. Wray's health care providers, wherein Defendants can question the physicians. Defendants have failed to establish that they are entitled in a federal proceeding to conduct secret meetings with Plaintiffs' health care providers.

II. CONCLUSION

For these reasons, Plaintiffs respectfully request that this Court deny Tennessee Clinic Defendant's Motion for a Qualified Protective Order.

Date: February 5, 2016

Respectfully submitted:

/s/ Annika K. Martin

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CERTIFICATE OF SERVICE

I, Annika K. Martin, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: February 5, 2016

/s/ Annika K. Martin